

ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

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IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 04/07/2020		2. CONTRACT NO. (If any) HHSO10020160005I		6. SHIP TO: a. NAME OF CONSIGNEE HHS/OS/ASPR		
3. ORDER NO. 75A50120F33010		4. REQUISITION/REFERENCE NO. OS256952		b. STREET ADDRESS 200 C St SW WASHINGTON DC 20201		
5. ISSUING OFFICE (Address correspondence to) US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515				c. CITY WASHINGTON		
				d. STATE DC		
7. TO: Bruce D'Arienzo		f. SHIP VIA		e. ZIP CODE 20201		
a. NAME OF CONTRACTOR PROTEIN SCIENCES CORPORATION 373074				8. TYPE OF ORDER		
b. COMPANY NAME		<input type="checkbox"/> a. PURCHASE REFERENCE YOUR:		<input checked="" type="checkbox"/> b. DELIVERY		
c. STREET ADDRESS PROTEIN SCIENCES CORPORATION 1 1000 RESEARCH PKWY				Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.		
d. CITY MERIDEN		e. STATE CT		f. ZIP CODE 064507149		
9. ACCOUNTING AND APPROPRIATION DATA See Schedule		10. REQUISITIONING OFFICE BARDA				
11. BUSINESS CLASSIFICATION (Check appropriate box(es)) <input checked="" type="checkbox"/> a. SMALL <input type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) VETERAN-OWNED <input type="checkbox"/> h. EDWOSB ELIGIBLE UNDER THE WOSB PROGRAM				12. F.O.B. POINT		
13. PLACE OF a. INSPECTION Destination		14. GOVERNMENT B/L NO.		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 10/07/2022		
b. ACCEPTANCE Destination				16. DISCOUNT TERMS		
17. SCHEDULE (See reverse for Rejections)						
ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number: 06-1098847 DUNS Number: 109124933 ASPR-20-01742 -- Protein Sciences Corporation is to conduct the non-clinical and Phase I clinical studies for a stabilized pre-fusion trimer of the spike protein Continued ...					
SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:				\$29,925,884.00	
	a. NAME PSC/FMS					\$29,925,884.00
	b. STREET ADDRESS PSC_invoices@psc.hhs.gov (or P.O. Box)					
c. CITY	d. STATE	e. ZIP CODE				
22. UNITED STATES OF AMERICA BY (Signature)		Wendell Conyers - S		23. NAME (Typed) WENDELL CONYERS TITLE: CONTRACTING/ORDERING OFFICER		
Digitally signed by Wendell Conyers -S Date: 2020.04.10 11:25:49 -04'00'						

**ORDER FOR SUPPLIES OR SERVICES
SCHEDULE - CONTINUATION**

PAGE NO
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IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 04/07/2020	CONTRACT NO. HHSO100201600005I	ORDER NO. 75A50120F33010
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
1	<p>COVID-19 vaccine candidate (the Candidate Vaccine) AS03 and AF03, for 2019 nCoV under contract HHSO100201600005I. Period of Performance: 04/07/2020 to 10/07/2022</p> <p>CLIN 1101 - Laboratory Testing / Assay (IAW Section E) Firm Fixed Price (FFP)</p> <p>Accounting Info: 2020.199COV1.25103 Appr. Yr.: 2020 CAN: 199COV1 Object Class: 25103 Funded: \$636,354.00</p>				636,354.00	
2	<p>CLIN 1201 - Animal Studies & Tox (IAW Section F) Firm Fixed Price (FFP)</p> <p>Accounting Info: 2020.199COV1.25103 Appr. Yr.: 2020 CAN: 199COV1 Object Class: 25103 Funded: \$10,618,801.00</p>				10,618,801.00	
3	<p>CLIN 1301 - Clinical Studies (IAW Section G) Firm Fixed Price (FFP)</p> <p>Accounting Info: 2020.199COV1.25106 Appr. Yr.: 2020 CAN: 199COV1 Object Class: 25106 Funded: \$18,670,729.00</p>				18,670,729.00	
4	<p>CLIN 1601 - Additional Reporting (IAW Section H) Firm Fixed Price (FFP)</p>				0.00	
5	<p>CLIN 1801 cGMP Vaccine Investigational Lot(s) (IAW Section C) Cost-Sharing (CS)</p> <p>Protein Sciences Corporation (PSC) has agreed to provide 100% funding toward this CLIN in the amount of \$4,381,782.00 to the existing Cost-Sharing Task Order.</p> <p>\$730,297.00 x 6 lots = \$4,381,782.00</p>				0.00	
6	<p>CLIN 0601 Formulation and Filling Antigen-Single dose vials (IAW Section D) Continued ...</p>				0.00	
TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))				\$29,925,884.00		

**ORDER FOR SUPPLIES OR SERVICES
SCHEDULE - CONTINUATION**

PAGE NO

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IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER CONTRACT NO.
04/07/2020 HHSO100201600005I

ORDER NO.
75A50120F33010

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	<p>Cost-Sharing (CS)</p> <p>Protein Sciences Corporation (PSC) has agreed to provide 100% funding toward this CLIN in the amount of \$2,296,000.00 to the existing Cost-Sharing Task Order.</p> <p>\$57.50 x 40,000 vials = \$2,296,000.00</p>					
7	<p>Adjuvant Drug Product AF03 (Sanofi) Cost-Sharing (CS)</p> <p>Protein Sciences Corporation (PSC) has agreed to provide 100% funding toward this CLIN in the amount of \$462,540.00 to the existing Cost-Sharing Task Order.</p> <p>\$177.90 x 2,600 vials = \$462,540.00</p> <p><u>Attachment:</u> Attachment 1 - Statement of Work</p> <p>The total amount of award: \$29,925,884.00. The obligation for this award is shown in box 17(i).</p>				0.00	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))



\$0.00

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Prescribed by GSA FAR (48 CFR) 53.213(f)

In addition to all terms and conditions of the Base Contract, the following Articles are also applicable to this task order.

ARTICLE B.2. PRICES

- a. The total fixed price of this task order (with the exception of CLINs 1801C, 0601 and Sanofi Adjuvant (AF03)) is **\$29,925,884.00**.
- b. Upon delivery and acceptance of the services described in SECTION K of the Business Proposal (in response to Request for Task Order (RTOR) # 2020-003 COVID-19 Candidate Vaccine Activities) and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

CLIN	SUPPLIES/SERVICES	UNIT	QUANTITY	UNIT PRICE	TOTAL EXTENDED PRICE
1101	Laboratory Testing / Assay	each	1	\$636,354	\$636,354
1201	Animal Studies & Tox	each	1	\$10,618,801	\$10,618,801
1301	Clinical Studies	each	1	\$18,670,729	\$18,670,729
1601	Additional Reporting		N/A	NSP	\$0
	Total Amount				\$29,925,884.00

- c. Upon delivery and acceptance of the services described in SECTION K of the Business Proposal (in response to RTOR # 2020-003 COVID-19 Candidate Vaccine Activities) and identified in the schedule of charges below, the Protein Sciences Corporation (PSC) is responsible and shall furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities to unit price(s) set forth below:

CLIN	SUPPLIES/SERVICES	UNIT	QUANTITY	UNIT PRICE	TOTAL EXTENDED PRICE	COST SHARE	
						PSC 100%	BARDA 0%
1801C	cGMP vaccine investigational lot(s)	lot(s)	6	\$730,297	\$4,381,782	\$4,381,782	\$0
0601	Formulation and Filling Antigen-Single dose vials	vials	Up to 40k (TBD)	\$57.40	\$2,296,000	\$2,296,000	\$0
N/A	Adjuvant Drug Product AF03 (Sanofi)	vials	2600	\$177.90	\$462,540	\$462,540	\$0
	Total Amount				\$7,140,322	\$7,140,322	\$0

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated **March 2020**, attached hereto and made a part of this Task Order (See SECTION J- List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

In addition to the requirements of the clause, REPORTING REQUIREMENTS AND DELIVERABLES, incorporated in SECTION F-3 of this contract, all reports required herein shall be submitted in electronic format via email as attachments to the followings:

1. Contracting Officer's Representative (COR) Bai Yen at Bai.Yeh@hhs.gov
2. Contracting Officer (CO) Wendell Conyers at Wendell.Conyers@hhs.gov
3. Contract Specialist (CS) at Di Ann Calderon Carty at Diann.CalderonCarty@hhs.gov

NOTE: Hard copies of reports are not required. Each email submission shall contain only one deliverable. If the attached file for the deliverable exceeds 50 MB, the Contractor shall divide the deliverable into files of 50 MB each. All deliverables should be limited to five file attachments or less. In cases where it is necessary, more than five attachments will be accepted.

The subject of the email shall read as follows:

Deliverable_Contract Number_Task Order Number_Vendor's Name_Deliverable Description_Due Date

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this Task Order shall be from April 7, 2020 through October 7, 2022.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the task order shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.O.B. destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

Adhere to Deliverables the Statement of Work, dated **March 2020**, attached hereto and made a part of this Task Order (See SECTION J- List of Attachments).

b. The above items shall be addressed and delivered to:

Addressee	Deliverable Items	Submit to:
Contracting Officer's Representative	All	Bai.Yeh@hhs.gov
Contracting Officer	All	Wendell.Conyers@hhs.gov
Contract Specialist	All	Diann.CalderonCarty@hhs.gov

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract task order:

Yeh Bai

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section G of the contract.

The Government may unilaterally change its COR designation.

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in the base contract and FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:
Contract Title: Acquisition of MCMs for Pandemic Influenza Preparedness and Response
Task Order Title: 2020-003 COVID-19 Candidate Vaccine Activities

ARTICLE G.6. GOVERNMENT PROPERTY

In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION G-7 of this contract, the contractor shall Reference Section C.2.3. Additional Requirements. Products manufactured and stored under this contract are 'Government Property'. These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under the license.

SECTION J – LIST OF ATTACHMENT

1. Statement of Work dated March 2020, 5 pages

END OF TASK ORDER 75A50120F33010

Statement of Work
March 2020

Phase 1 Clinical Development of a COVID-19 Candidate Vaccine

Background

The United States Department of Health and Human Services (HHS) continuously monitors emerging infectious disease risk and prepares to respond to the threat of novel emerging infectious disease outbreaks in the United States.

HHS is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China and which has now spread to 156 countries or territories, including in the United States. The virus has been named “SARS-CoV-2” and the disease it causes has been named “coronavirus disease 2019” (abbreviated “COVID-19”).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “public health emergency of international concern” (PHEIC). On January 31, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nation’s healthcare community in responding to COVID-19. On March 11, WHO publicly characterized COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a national emergency.

Coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS, SARS, and now with SARS-CoV-2.

Vaccination is often the most effective measure for the control of infectious diseases. The best strategy for rapid development, production, and administration of a COVID-19 vaccine entails leveraging existing vaccine platform technologies. Development efficiency is accelerated by drawing on approaches used for related coronaviruses. Therefore, as part of HHS preparedness and response activities, HHS seeks to accelerate COVID-19 vaccine development by supporting Phase 1 clinical development of Protein Sciences Corporation’s recombinant DNA platform technology.

Project Scope

Objectives:

1. cGMP vaccine investigational lot(s)
 - a. manufacture the clinical vaccine lot in manufacturing facilities according to cGMP under 21 CFR parts 210, 211, and 600
 - b. Perform lot release product testing of cGMP SARS-CoV-2 recombinant spike protein vaccine.
 - c. Make batch records available for review by HHS.
 - d. Set aside samples for stability testing up to 60 months.
2. Formulation and filling antigen in single-dose vials

cGMP SARS-CoV-2 recombinant spike protein vaccine manufactured under aseptic conditions will be formulated into single-dose vials.

- a. Aseptic process development may be proposed.
- b. Multiple formulations filled into single dose vials per formulation are required.

- c. Full release testing, including potency, of the final drug product should be proposed.
- 3. Animal Studies
 - Evaluation of vaccine safety and efficacy in animal studies should be proposed to support Phase 1 clinical development.
 - a. Multiple animal models may be proposed.
 - b. Testing for the potential of vaccine-enhanced disease is required.
 - c. Testing of adjuvants for enhancement of effectiveness and antigen-sparing, as well for effect on vaccine-enhanced disease is required: it is likely that multiple adjuvants will be assessed – these may be suggested and/or supplied by BARDA.

4. Clinical Study

Conduct a Phase 1 clinical study to test the safety, dose, schedule, and immunogenicity of the vaccine candidate to support entering Phase 2/3 clinical studies.

- a. Qualified and/or validated immunogenicity assays are required.
- b. A plan to assess the duration of immunogenicity is required.
- c. The need for adjuvant is likely.
- d. Additional serum samples should be collected and stored for future use. These samples and associated data will be transferred to a BARDA-managed repository at a future date to be determined.
- e. Plan to publish study findings in a peer-reviewed journal

Conditions:

1. Animal studies may include a toxicology study.
2. Stability testing on the final drug substance and drug product will be performed. The number of samples to be set aside for stability study testing should be sufficient for at least 60 months of testing.
3. Regulatory documents to support an Investigational New Drug (IND) application (e.g., Investigator's Brochure (IB), letters of authorization (LOA) to cross reference Biologics Master File (BMF), stability, Module 3 CMC documents, etc.) will be provided to BARDA.
4. Provide stability testing results to BARDA on a frequency and a duration requested by BARDA, with immediate notification to BARDA of any out of specification results during stability testing.

Anticipated Period of Performance

The period of performance is approximately 24 months

Deliverables

1. Final Report for Aseptic Process Development if required
2. Certificates of Analysis
3. Certificates of Compliance
4. Draft and Final Reports for formulation and filling of drug product
5. Animal Studies:
 - a. Draft and Final Protocols
 - b. Quality Assurance Plan(s)
 - c. Draft and Final Study Reports

Draft Statistical Analysis Plan	90 days post award
Final Statistical Analysis Plan	Prior to database lock
Interim reports for primary immunogenicity endpoint*	Within 24 weeks of primary immunogenicity endpoint
SAEs related to the product during the entire duration of the study	Within 24 hours of SAE notification to Sponsor
Enrollment updates	Bi-weekly while enrollment is ongoing, monthly after enrollment complete
Safety information**	Monthly
Investigator Brochure	Due: With the final protocol
Clinical Site information	Due: With the final protocol
Final Clinical Study Report	Within 6 months of study completion
Final data package submitted to FDA	Within 7 months of study completion

*Interim report should include a summary of safety and immunogenicity data.
 **Monthly safety report is a listing of all SAEs regardless of relationship to the product.

Additional Requirements

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	Meetings		
01.6	Daily check in with project staff for COVID-19 Contract	<p>Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email).</p> <p>The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID-19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats.</p> <p>Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on</p>	<ul style="list-style-type: none"> • No agenda will be required for the meeting • No meeting minutes are required • Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Federal holidays, provided at least 24 hours' notice.	
02	Technical Reporting		
02.8	Product Development Source Material and Manufacturing Report	The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.	<ul style="list-style-type: none"> Contractor will submit Product Development Source Material Report <ul style="list-style-type: none"> Within month of contract award Within 30 days of substantive changes are made to sources and/or materials Or on the 6th month contract anniversary. The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing
02.9	Contractor Locations	The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.	<p>Contractor will submit Work Locations Report:</p> <ul style="list-style-type: none"> Within 5 business days of contract award Within 30 business days after a substantive location or capabilities change Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

Place of performance

Contractor facilities or Subcontractor facilities

Government Property

Reference Section C.2.3. Additional Requirements. Products manufactured and stored under this contract are 'Government Property'. These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under the license.